

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LINDA ROSI, Individually and On
Behalf of All Others Similarly Situated,

Plaintiff,

v.

ACLARIS THERAPEUTICS, INC.,
NEAL WALKER, FRANK RUFFO,
KAMIL ALI-JACKSON, and BRETT
FAIR

Case No.: 1:19-CV-7118 (LTS) (JLC)

CLASS ACTION

**AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS
OF THE FEDERAL SECURITIES
LAWS**

JURY TRIAL DEMANDED

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Lead Plaintiff Robert Fulcher (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon his personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Aclaris Therapeutics, Inc. (“Aclaris” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

Counsel for Plaintiff has conducted extensive due diligence in preparation of this Amended Class Action Complaint (“Complaint”). Plaintiff, among other things, retained the services of an independent investigation firm with extensive investigative experience, which made significant efforts to identify, locate, contact and interview former employees of Defendants potentially relevant information to the allegations in this Amended Complaint.

I. NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of a class (the “Class”) of persons and entities that purchased or otherwise acquired Aclaris securities between May 8, 2018 and August 12, 2019, inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. Aclaris is a small biopharmaceutical company that is headquartered in Wayne, Pennsylvania. During the Class Period, the Company purported to identify, develop, and commercialize therapies to address unmet needs in medical and aesthetic dermatology and immunology. Aclaris's common stock is listed on the NASDAQ Global Select Market under the symbol "ACRS."

3. This case arises out of Defendants' shameless scheme to market Aclaris's leading product, ESKATA, a topical treatment for common benign skin lesions, by misrepresenting ESKATA's risks, tolerability and effectiveness. When the truth about ESKATA and Defendants' scheme emerged, Defendants had no choice but to stop marketing ESKATA and Aclaris's stock plummeted, causing significant damage to investors.

4. The FDA approved ESKATA on December 14, 2017, five months before the start of the Class Period. ESKATA is a high-concentration (40%) hydrogen peroxide-based topical solution for treatment of raised seborrheic keratosis ("raised SK"), or waxy or wart-like raised brown spots or lesions on the skin that are darker than an individual's regular skin tone. Since ESKATA was Aclaris's only FDA-approved product at the time, it was thus far and away the Company's most important product. The Company's ability to continue as a going concern depended on whether Defendants could successfully market ESKATA.

5. Defendants emphasized to investors that Aclaris could reap windfall profits through ESKATA sales because the product filled a gap in the billion-dollar cosmetic dermatology market. Defendants told investors that existing raised SK treatments—freezing, cutting or burning off the lesions—were avoided by consumers because they were invasive, painful and could leave scars or skin discolorations. Unlike existing SK treatments, Defendants claimed, ESKATA was "an appealing concept for SK treatment" because it was "[t]opical, non-

invasive,” involved “minimal discomfort” and resulted in “[r]educed risk of pigmentary changes and scarring.”

6. Based on these representations, the market was excited by ESKATA’s commercial potential. On January 8, 2018, a William Blair analyst predicted “peak-year sales” of ESKATA “that could approximate \$600 million with *relatively modest penetration assumptions* (about 20%)” (emphasis added). Similarly, on March 12, 2018, a Guggenheim Partners analyst advised investors that ESKATA could reach sales of *\$576 million in the United States alone* by 2025 (emphasis added).

7. Defendants implemented a two-phase plan for marketing ESKATA. In the first phase, called the “ESKATA Early Experience Initiative,” Aclaris sales representatives visited physicians to persuade them to order ESKATA. The sales representatives offered free samples of ESKATA and sat in when the physicians administered the samples to patients. After the treatments, sales representatives surveyed the physicians and patients on, among other things, a patient’s pain or comfort level and how effectively ESKATA removed raised SK.

8. The second phase of the ESKATA marketing process, a direct-to-consumer marketing campaign (the “DTC campaign”) was designed to drive patients to physicians to request ESKATA treatments. The DTC campaign kicked off on or about September 19, 2018 when a scripted mock “interview” with a paid ESKATA spokesperson aired on the daytime talk show “The View.” After the staged interview segment aired, Defendants made a recording of the segment available online on web pages promoting ESKATA on Facebook.com and LinkedIn.com, and released print advertising and a 60-second television commercial promoting ESKATA as a low-risk and effective way to remove raised SK.

9. When the ESKATA Early Experience Initiative began in spring 2018 sales representatives were stunned to discover that ESKATA did not completely remove raised SK lesions, was painful and left persistent skin discoloration. Multiple confidential witnesses (“CWs”) who worked as ESKATA sales representatives described how patients found ESKATA painful. One CW, for example, said that ESKATA’s adverse effects were “more severe than anyone was prepared for” and included swelling and bubbling “as if the skin was burning.” Another CW described at least one patient stopping ESKATA treatments because of pain and fielded so many complaints from physicians and patients about pain that he began providing his own *ad hoc* warnings about pain management to physicians and office staff when selling the product. Areas treated with ESKATA were frequently marked by skin discoloration as well. As one CW and former sales representative put it, although Defendants were marketing ESKATA “as a safer, easier, non-invasive alternative to competitors, in reality, it had the same side effects as existing methods of removing SKs but was more expensive.”

10. Sales representatives discussed ESKATA’s limited efficacy, pain and skin discoloration during regular internal calls and meetings. Senior Aclaris executives attended these calls and reported those incidences up to the highest levels of the Company, including the Individual Defendants. Although Defendants had actual knowledge that ESKATA treatments was limited in effectiveness, extremely painful and left skin discolorations, they misrepresented to investors that ESKATA was well-tolerated and effective, thus concealing the risk that ESKATA could not be successfully commercialized since it was limited in effectiveness, painful, left skin discoloration and thus was no better than existing alternatives.

11. For example, on the first day of the Class Period, May 8, 2018, Defendants held an earnings call to report the Company’s performance for the first quarter of 2018 (the “Q1 2018

Call”). On that call, Defendants outright lied, telling investors that “[t]he patients *enjoy* [ESKATA], seems to be a *comfortable* treatment” (emphasis added). Defendants also misleadingly presented the results of physician and patient surveys that sales representatives had taken during the ESKATA Early Experience Initiative. Defendants told investors, among other things, that the initiative surveys showed that “[t]he patient feedback is also *very encouraging*” and that an overwhelming majority of patients found the treatment easy, “were comfortable enough with their appearance to go out socially,” and would recommend ESKATA to their friends. These statements were false and misleading because Defendants knew from reports from sales representatives that patients found ESKATA treatments painful, were upset by the skin discolorations that persisted after treatments and were dissatisfied with ESKATA’s failure to completely remove raised SK. These statements also concealed the risk that ESKATA was not commercially viable. In the days following these disclosures, Aclaris’s share price soared 7.9% from \$18.01 per share to \$19.44 per share.

12. Defendants made similar false and misleading statements on an August 8, 2018 earnings call to disclosing the Company’s performance for the second quarter of 2018 (the “Q2 2018 Call”). Instead of disclosing the truth about how patients were reacting to ESKATA, Defendants told investors that ESKATA “*really works* and . . . [T]hat sets us up really well for the long term It’s a *comfortable* treatment, *it’s easy, it’s quick, and the patients look good, the next day it resolves well.*” Defendants also purported to provide “updated” ESKATA Early Experience Initiative survey results and again claimed, among other things, that an overwhelming majority of patients found the treatment easy, “were comfortable enough with their appearance to go out socially,” and would recommend ESKATA to their friends. These statements were also false and misleading because Defendants knew from reports from sales

representatives that patients found ESKATA treatments painful, were upset by the skin discolorations that persisted after treatments and were dissatisfied with ESKATA's failure to remove raised SK. These statements also concealed the risk that ESKATA was not commercially viable. In the aftermath of these disclosures, Aclaris's share price briefly rose from 0.5% from \$17.37 per share to \$17.46 per share.

13. Unsurprisingly, given these complaints to sales representatives, ESKATA's sales collapsed during the Class Period. While analysts, based on Defendants representations, had predicted that ESKATA would achieve anywhere from \$9.8 million to \$20.7 million in sales during 2018 alone, Defendants reported only **\$3.2 million** in sales of ESKATA from the second quarter of 2018 (the first three months the product was available) to the second quarter of 2019.

14. Defendants never disclosed to the public that ESKATA's sales were poor because ESKATA was limited in effectiveness, extremely painful and left skin discolorations. Instead, Defendants audaciously told investors that ESKATA's sales poor because the product *was working too well*. On an earnings call with analysts on November 6, 2018, while reporting Aclaris's earnings for the third quarter of 2018 (the "Q3 2018 Call"), Defendants claimed that ESKATA's shockingly low sales were because the product was "actually clearing lesions a ***lot quicker, one to two times,***" *i.e.*, in only one or two visits to a physician. This statement was false and misleading because Defendants knew from reports from sales representatives that ESKATA's lagging sales were because the treatment was limited in effectiveness, painful and left persistent skin discolorations. Defendants also knew this was false, because they had attended a meeting of an "executive sales team" of high-performing sales representatives between August and October 2018 where the sales representatives discussed complaints from physicians, among other things, the complaints sales representatives had received from

physicians and patients about adverse side effects and that ESKATA was not effective, including that ESKATA took many *more* applications to achieve any results than the physicians had been told when they were sold the product. It also concealed the risk that ESKATA was not commercially viable. In response to this disclosure, Aclaris's share price briefly rose 2.2% to \$12.01 per share.

15. At the same time Defendants were misleading investors about patients' reactions to ESKATA and ESKATA's declining sales, Defendants also concealed from investors that their DTC campaign materially misled patients about ESKATA's risks and effectiveness. The Federal Food, Drug and Cosmetics Act ("FFDCA") prohibits making false or misleading claims and/or representations about the risks associated with and the efficacy of pharmaceuticals and medical devices. In direct contravention of the FFDCA, Defendants used marketing materials in their DTC campaign that failed to disclose serious risks associated with ESKATA, created misleading impressions about ESKATA's common adverse reactions and/or misleadingly represented that patients treated with ESKATA would experience complete clearance of all treated raised SK. Although Defendants knew that their ESKATA DTC campaign materially misled patients and violated the FFDCA, they nevertheless touted the success of the DTC campaign without disclosing these facts.

16. For example, Defendants launched the DTC campaign with a scripted segment that aired on the daytime talk show "The View" on or about September 19, 2018. The segment, which consisted of a host of The View "interviewing" a paid Aclaris spokesperson, misrepresented ESKATA's risk profile because it did not disclose that ESKATA presents both a serious risk of major eye disorders and severe skin reactions. The segment also misrepresented ESKATA's risks by suggesting only that patients may experience "stinging" during treatment,

when ESKATA also frequently causes skin discoloration, scaling and crusting that could persist for months. Defendants knew that ESKATA presented these risks because the FDA had required Defendants to include warnings of these risks on ESKATA's packaging and/or package insert.

17. Further, the segment misrepresented ESKATA's efficacy by suggesting that a typical patient would have all of their treated lesions completely removed without scarring or skin discoloration. During the segment, Aclaris's paid spokesperson told consumers, "typically in one or two treatments the lesions go away, they resolve, and that's the end of it" and showing viewers "before-and-after" photos purporting to depict patients with multiple raised SK who had their lesions completely removed without scarring. Defendants knew that these statements were false and misleading because ESKATA's clinical trials had shown that only 4%–8% of patients saw complete clearance of lesions, and sales representatives had repeatedly reported complaints from physicians and patients to Defendants about ESKATA's effectiveness at removing SK lesions. Although the before-and-after images were accompanied by a disclaimer that "18% of patients who experienced clearance of 3 of 4 raised SKs treated with ESKATA as compared to 0% with vehicle (Day 106 end of study)," that disclaimer only appeared on screen briefly during the segment and the before and after images were much larger and more prominent. The print and television advertising that Defendants used in their DTC campaign also misled patients about ESKATA's effectiveness by improperly using one of the sets of before-and-after images that were used in the segment on The View.

18. Defendants knew that their advertising misrepresented ESKATA's effectiveness because federal regulators had warned Defendants about using marketing materials that omitted or misrepresented material information regarding ESKATA's risks and that overstated ESKATA's effectiveness. For example, on March 29, 2018, as the ESKATA Early Experience

Initiative was under way, the FDA’s Office of Prescription Drug Promotion (“OPDP”) provided advisory comments to Defendants on proposed presentations promoting ESKATA (the “March 2018 Letter”). The OPDP directed Defendants to revise the presentations so that they did not “omit material information regarding the risks associated with ESKATA or otherwise misrepresent important risk information” and “overstate the efficacy of ESKATA.” Defendants never disclosed the March 2018 Letter to investors.

19. Defendants also knew that their direct-to-consumer marketing campaign misrepresented ESKATA’s risks and efficacy because Aclaris’s former Executive Director of Medical Affairs and the Company’s former publications manager each repeatedly voiced concerns that were raised to Defendants that the Company’s marketing materials for ESKATA were misrepresenting the product’s safety and effectiveness.

20. Although Defendants knew that their direct-to-consumer advertising campaign misrepresented the risk and efficacy of ESKATA in violation of federal law, Defendants never disclosed this fact to investors. Instead, Defendants touted to investors how the DTC campaign was generating interest in ESKATA. For example, on the Q3 2018 Call, Defendants touted to investors that the segment on “The View” advertising ESKATA to consumers was driving interest in the product. Defendants told investors, in response to an analyst’s question, that, “we’ve seen a big spike in, obviously, in the website traffic results over the course of October, *saw a big spike with The View and then we’ve seen that big spike continue to grow in the month of October.* That’s a good sign.” These statements were misleading because Defendants did not disclose that their advertising campaign had created these spikes in Internet traffic and interest in ESKATA by misrepresenting the risks and efficacy of the treatment in violation of the FFDCA. The statements also concealed the risk that ESKATA was not commercially viable and

could only be effectively marketed using materials that misrepresented ESKATA's risks and efficacy. In response to this disclosure, Aclaris's share price briefly rose 2.2% to \$12.01 per share.

21. Defendants' failure to disclose that their DTC campaign was misleading patients as to the risks and efficacy of ESKATA also rendered Aclaris's risk factors contained in annual reports on Forms 10-K that the Company filed with the SEC during the Class Period misleading because the risk factors misrepresented and/or failed to disclose that Aclaris's share price could experience volatility and that Aclaris could be subject to regulatory action as a result of Defendants' misleading DTC campaign that violated the FFDCA.

22. Investors learned that Defendants' DTC campaign misrepresented the risks and efficacy of ESKATA and violated the FFDCA on June 20, 2019, when the FDA publicly disclosed that it had sent Defendants an "untitled letter" (the "June 2019 Letter") finding that the staged interview segment on The View violated the FFDCA. A further corrective disclosure followed when Defendants announced on August 8, 2019 that Aclaris was abandoning commercialization of ESKATA because of "insufficient market acceptance," effectively admitting that patients would not use the product and ESKATA was not commercially viable.

23. The OPDP's June 2019 letter disclosed that the segment on The View violated the FFDCA by "fail[ing] to include information regarding the serious risks associated with ESKATA, which bears warnings and precautions related to the risks of serious eye disorders . . . and severe skin reactions." The June 2019 Letter also stated that the segment's use of before and after photographs violated the FFDCA by "misleadingly represent[ing] that the typical patient treated with ESKATA will experience similar results, *i.e.*, complete clearance of all treated SK lesions." The June 2019 Letter directed Defendants to stop using the segment to promote

ESKATA, submit a written response to the OPDP and provide a list of all ESKATA advertising materials for ESKATA that violated the FFDCA.

24. On this news, the Company's share price fell \$0.57 per share, or over 11%, over two consecutive trading sessions to close at \$4.54 per share on June 21, 2019, on unusually heavy trading volume.

25. With the truth about their DTC campaign exposed, Defendants knew that they needed to destroy their marketing materials because those materials misled investors as to ESKATA's efficacy and violated the FFDCA. Indeed, within days of the June 2019 Letter, Defendants scrubbed the recording of the segment from The View from sales representatives iPads and the Internet and then instructed sales representatives to destroy *all* ESKATA marketing materials.

26. Defendants also knew that any advertising campaign for ESKATA that was consistent with the FFDCA would need to disclose that ESKATA was limited in effectiveness, painful and resulted in skin discoloration. Defendants also knew that disclosing these facts meant that they could not successfully market ESKATA because these disclosures would confirm that ESKATA was no better than any other treatment for raised SK and had all the downsides that Defendants' own research showed resulted in patients deciding not to treat their raised SK. Defendants had attempted to conceal the risk that ESKATA was not commercially viable, but that risk had now materialized.

27. On August 8, 2019, Defendants issued a press release announcing Aclaris's financial results for the second quarter of 2019. The press release also disclosed that the Company was "[v]oluntarily discontinuing the commercialization of ESKATA® (hydrogen peroxide) Topical Solution, 40% (w/w) (ESKATA) in the United States due to the fact that

revenues from product sales were insufficient for Aclaris to sustain continued commercialization as a result of the product not achieving sufficient market acceptance by physicians and patients.” This was a materialization of the risk that Defendants would need to abandon ESKATA because the product was limited in effectiveness, painful and resulted in skin discoloration.

28. On this news, the Company’s share price fell \$0.15 per share, or over 14%, over two consecutive trading sessions to close at \$0.84 per share on August 12, 2019, on unusually heavy trading volume.

29. Throughout the Class Period, Defendants disseminated materially false and misleading statements and failed to disclose material adverse facts about Aclaris’s business, operations, and prospects. Specifically, Defendants (i) falsely and misleadingly told investors that patients “enjoyed” ESKATA, found it “comfortable,” and that the treatment “works” and “resolves well,” (ii) disclosed the results of “surveys” that misleadingly suggested that ESKATA was effective and tolerated well by patients, when in fact physicians and patients found the treatment painful and/or limited in effectiveness, (iii) falsely attributed ESKATA’s poor sales to the fact that patients needed fewer treatments than expected to remove their raised SK, (iv) falsely and misleadingly touted the Company’s DTC advertising campaign while failing to disclose that the campaign was designed to mislead patients as to the risks and effectiveness of ESKATA in violation of the FFDCA, and (v) failed to disclose the risk of regulatory action created by Defendants’ violations of the FFDCA.

30. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

31. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

32. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

33. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

34. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

35. Plaintiff, as set forth in the certification accompanying the filing of his initial complaint in this action, *see* Complaint at 24, *Fulcher v. Aclaris Therapeutics, Inc., et al.*, No. 1:19-cv-08284-JTS-JLC (S.D.N.Y. Sept. 5, 2019), ECF No. 1, incorporated by reference herein, purchased Aclaris securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

36. Defendant Aclaris is incorporated under the laws of Delaware with its principal executive offices located in Wayne, Pennsylvania. Aclaris' shares trade on the NASDAQ Global Select Market under the symbol "ACRS."

37. Defendant Neal Walker ("Walker") was the President and Chief Executive Officer ("CEO") of the Company at all relevant times. Aclaris identified Walker as an "Executive Officer" of the Company during the Class Period.

38. Defendant Frank Ruffo ("Ruffo") was the Chief Financial Officer ("CFO") of the Company at all relevant times. Aclaris identified Ruffo as an "Executive Officer" of the Company during the Class Period.

39. Defendant Kamil Ali-Jackson ("Ali-Jackson") was the Chief Legal Officer, Chief Compliance Officer and Corporate Secretary (collectively, "CLO") of the Company at all relevant times. Aclaris identified Ali-Jackson as an "Executive Officer" of the Company during the Class Period.

40. Defendant Brett Fair ("Fair") was the Chief Commercial Officer ("CCO") of the Company throughout the Class Period until February 8, 2019, when Aclaris disclosed in a Current Report on Form 8-K filed with the SEC "[e]ffective as of February 7, 2019" that Fair was "no longer employed by the Company." Aclaris identified Fair as an "Executive Officer" of the Company during the Class Period under February 7, 2019.

41. Defendants Walker, Ruffo, Ali-Jackson and Fair (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's public statements, reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports

and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. Further, as set forth herein, each of the Individual Defendants either made the fraudulent statements that defrauded the class, were present when the fraudulent statements were made and failed to correct those statements or actively conspired to create the fraudulent statements and/or conceal the truth from investors and thus culpably participated in the misstatements and omissions that defrauded Plaintiff and the other members of the Class. The Individual Defendants are liable for the false statements pleaded herein.

IV. CONFIDENTIAL WITNESSES

42. In connection with its investigation of this matter, an independent investigation firm retained by Plaintiff interviewed a number of former Aclaris employees identified herein as confidential witnesses (“CWs”). All confidential witnesses are referred to in the masculine to protect their identities.

43. CW1 was a director of project management at Aclaris at its headquarters from February 2017 until October 2019. CW1 focused on managing work groups at the Company responsible for clinical trials of Aclaris’s drug candidates. CW1 reported to Aclaris’s VP of Project Management.

44. CW2 was the Vice President of Pharmaceutical Development and Manufacturing at Aclaris at its headquarters from February 2017 until September 2018. CW2 focused on managing work groups responsible for clinical trials of Aclaris’s drug candidates. CW2 reported to Aclaris’s Chief Operating Officer Christopher Powala. Powala served as an Executive Officer

of the Company during the Class Period together with the Individual Defendants. CW2's work involved correspondence with the FDA regarding the packaging, manufacturing and product instructions for ESKATA.

45. CW3 was a sales representative at Aclaris from January 2018 until September 2019. He was hired to cover a territory in Florida and was later promoted to regional sales manager for the southeastern United States. CW3 was hired to contact physicians who could be interested in making ESKATA treatments available to patients. CW3 was also part of the first group of sales representatives to be trained in ESKATA sales in January 2018 before the product launched in May 2018. CW3 also met with and trained physicians and non-physician staff on how to use ESKATA. After his promotion, CW3's responsibilities expanded to include overseeing other sales representatives.

46. CW4 was a sales representative at Aclaris covering a regional territory in South Carolina from January 2018 until November 2018. CW4 was hired to contact physicians who could be interested in making ESKATA treatments available to patients. CW4 was also part of the first group of sales representatives to be trained in ESKATA sales in January 2018 before the product launched in May 2018. CW4 also met with and trained physicians and non-physician staff on how to use ESKATA.

47. CW5 was an account specialist at Aclaris covering a regional sales territory of Miami, Florida, and nearby areas from January 2018 until June 2019. CW5 was hired to contact physicians who could be interested in making ESKATA treatments available to patients. CW5 was also part of the first group of sales representatives to be trained in ESKATA sales in January 2018 before the product launched in May 2018. CW5 also met with and trained physicians and

non-physician staff on how to use ESKATA. CW5 has 18 years of experience in pharmaceutical sales.

48. CW6 was the publications manager at Aclaris at its headquarters from August 2018 until April 2019. CW6 oversaw Aclaris's publication of clinical trial results for ESKATA and other drug candidates and reported to Aclaris's medical director, who reported to Defendant Walker. CW6 has more than 20 years of experience in medical writing and publications.

49. CW7 was the Executive Director of Medical Affairs at Aclaris at its headquarters from April 2018 until September 2019. CW7 has over 20 years of experience in the pharmaceutical industry. CW7 reported to Aclaris's chief medical officer, who reported to Defendant Walker. As Executive Director of Medical Affairs, CW7 oversaw Aclaris's medical publications, medical science, medical information and independent medical investigations. This included working on abstracts, printed materials and articles published about Aclaris. CW7 also managed Aclaris's medical liaison staff, which was responsible for talking to healthcare providers and medication prescribers about off-label uses for Aclaris's products. Aclaris's director of medical information reported directly to CW7. Aclaris's director of medical information was a liaison between doctors and other divisions in the Company. The director of medical information personally attended twice-weekly Promotions, Regulatory and Compliance meetings at the Company.

50. CW8 was a sales manager at Aclaris covering a regional territory in Connecticut from October 2017 until November 2018. CW8 was hired to contact physicians who could be interested in making ESKATA treatments available to patients. He also supervised other sales representatives CW8 was also part of the first group of sales representatives to be trained in

ESKATA sales in January 2018 before the product launched in May 2018. CW8 also met with and trained physicians and non-physician staff on how to use ESKATA.

51. CW9 was a sales representative at Aclaris covering a regional territory from January 2018 until September 2019. His primary territory was in North Carolina. CW9 was hired to contact physicians who could be interested in making ESKATA treatments available to patients. CW9 was also part of the first group of sales representatives to be trained in ESKATA sales in January 2018 before the product launched in May 2018. CW9 also met with and trained physicians and non-physician staff on how to use ESKATA. CW9 has 10 years of industry experience as a sales representative in pharmaceutical sales, specifically in aesthetic products, and has trained other teams on administering aesthetic medications.

V. SUBSTANTIVE ALLEGATIONS

A. Aclaris

52. Aclaris is a microcap¹ biopharmaceutical company that identifies, develops, and commercializes therapies to address unmet needs in immunology. Until August 2019, Aclaris also focused on identifying, developing and commercializing therapies to address unmet medical and aesthetic dermatology needs in addition to immunology therapies.

53. Aclaris was incorporated under the laws of the State of Delaware in 2012 and completed an initial public offering in October 2015. The Company's common stock is listed on the NASDAQ Global Select Market under the symbol "ACRS."

54. Defendants Walker, Ruffo and Ali-Jackson closely managed the Company's operations during the Class Period. According to CW2, Walker, Ruffo and Ali-Jackson had known each other from working together at prior pharmaceutical start-up companies and, as the

¹ A "microcap" company is a publicly traded company in the United States that has a market capitalization between approximately \$50 million and \$300 million.

co-founders of Aclaris, they, together with Chief Operating Officer Chris Powala, “ran [Aclaris] and [] acted as the core management of the company.” CW2 said that Defendants Walker and Ruffo were very involved and knowledgeable about all of the Company’s products and marketing programs, but were particularly knowledgeable of ESKATA “because it was the company’s first commercial product to hit the marketplace.” CW6 also described Walker, Ruffo and Ali-Jackson as being heavily involved in every aspect of Aclaris.

55. Aclaris had only a small number of employees during the Class Period. For example, shortly before the Class Period began, the Company reported that, as of December 31, 2017, it had 96 full-time and part-time employees. A year later, the Company reported that it had 169 full-time and part-time employees as of December 31, 2018. As described in more detail below, when Defendants were forced to abandon marketing Aclaris in August 2019 after the scheme to market Aclaris to patients using misleading advertising that violated federal law, Defendants laid off approximately 86 employees, *i.e.*, over half the Company’s staff.

56. Aclaris was in dire financial condition at the start of the Class Period. The Company had never produced any revenue from product sales and was experiencing ever-increasing operating losses, which had ballooned from \$8.5 million in 2014 to \$72.4 million in 2017 to \$30.9 million in the *first quarter* of 2018 alone.

57. Since Aclaris did not sell any products, Defendants had funded the Company’s operations with funds it obtained from the Company’s initial public offering (“IPO”) in 2015 and a series of follow-on offerings. For example, the Company closed a private placement in June 2016 in which it sold an aggregate of 1,081,082 shares of common stock at a price of \$18.50 per share and reaped net proceeds of \$18.5 million. Six months later, in November 2016, the Company closed a public offering in which it sold 4,600,000 shares of common stock at a price

to the public of \$22.75 per share and reaped net proceeds of \$98.2 million. In August 2017, the Company closed still yet another follow-on public offering in which it sold 3,747,602 shares of common stock at a price to the public of \$23.02 per share and reaped net proceeds of \$80.9 million. Defendants knew, however, that the Company could not continue funding its operations through follow-on stock offerings in perpetuity. For the Company to continue operating as a going concern, Defendants had to successfully commercialize a product.

B. Raised Seborrheic Keratosis

58. Raised SK are benign raised brown spots on the skin that look waxy or wart-like, are darker than an individual's regular skin tone and generally grow and increase in size with age. Raised SK lesions usually appear on a person's face, hairline and neck, and can also appear on a person's chest and back. Patients can also have many lesions; according to an October 2015 article published in the Journal of Drugs and Dermatology, 33% of SK patients have more than 15 SK lesions. The lesions are colloquially known as "age spots" or, more pejoratively, as "barnacles" or "senile warts."

59. Although they are non-cancerous, raised SK are extremely common and affect approximately 83 million Americans. Since the lesions get larger, darker and thicker over time, dermatologists and/or other physicians constantly receive prospective patients seeking to have the lesions removed or otherwise treated because the lesions are unsightly or for fear that they are cancerous.

60. According to the IMS National Disease and Therapeutic Index 2016, dermatologists manage the majority of SK cases (approximately 80%), and primary care physicians usually refer patients to dermatologists for treatment. Dermatologists and/or other physicians usually remove raised SK by freezing them off ("cryosurgery"), but also can remove

them by cutting (“shave excision”), scraping and burning (“electrodessication and curettage”) or a combination thereof.

61. Patients avoid treatments like cryosurgery, shave excision and electrodessication and curettage, though, because the treatments are painful, leave scars and/or cause skin discoloration, including hypopigmentation, which is a term for patches of skin that are lighter than a person’s overall skin tone. Not only are these treatments painful and result in scarring and/or skin discoloration, but patients almost always pay out of pocket for the procedures. Since the lesions are benign, health insurance providers consider the procedures to be cosmetic, not medical, and do not cover procedures to remove them.

C. ESKATA

62. ESKATA is a high-concentration (40%) hydrogen peroxide-based topical solution specifically indicated for the treatment of raised SK. ESKATA was the first topical treatment for raised SK approved by the FDA, and as well as was the first product developed by Aclaris to receive FDA approval. Since ESKATA was Aclaris’s only FDA-approved product at the time, it was thus far and away the Company’s most important product. The Company’s ability to continue as a going concern depended on whether Defendants could successfully market ESKATA.

63. ESKATA is dispensed using an applicator that looks like a thin felt-tipped pen or highlighter. After a healthcare provider (usually a dermatologist) has determined that a spot or lesion on a patient’s skin is not cancer, a member of the healthcare provider’s staff “treats” the raised SK with ESKATA by rubbing the tip of the applicator “using firm pressure” directly on the lesion in a circular motion for approximately 20 seconds to coat the lesion with ESKATA. Each lesion is coated with ESKATA four times, approximately one minute apart. ESKATA moistens the lesion to dissolve the raised SK, while purportedly not damaging the surrounding

skin, and in the days following treatment the raised SK treated with ESKATA peels away. If the lesion is not removed by a single treatment, a patient is supposed to return for additional treatments.

64. Although the FDA had approved ESKATA, it nevertheless required Defendants to include prominent safety and adverse reaction warnings on ESKATA's label, packaging and package insert. For example, since ESKATA was a concentrated hydrogen peroxide solution, there was a risk of severe eye damage if any of the solution came into contact with a patient's eyes. Since raised SK commonly appear on a patient's face, there was a risk of eye damage associated with most ESKATA treatments. Accordingly, only a trained technician (either a physician or trained physician's assistant or staff member) was permitted to apply ESKATA. The drug's label and packaging warned "[e]ye disorders including corneal injury (erosion, ulceration, perforation, and scarring), chemical conjunctivitis, eyelid edema, severe eye pain, or permanent eye injury, including blindness can occur after exposure." The FDA also required ESKATA's label and packaging to warn of severe skin reactions, including "ulcerations and scarring."

65. Despite these risks, Defendants emphasized to investors that ESKATA could enable Aclaris to reap windfall profits because the product filled a gap in a billion-dollar market. For example, Defendants told investors in marketing presentations in late 2017 and early 2018 that the global dermatology market was valued at \$20 billion in 2015, the global aesthetic dermatology market was expected to reach \$13.29 billion by 2021 and non-surgical dermatological procedures had increased by 650% from 1997–2016. Moreover in annual reports on Form 10-K that Aclaris filed for the years 2015, 2016 and 2017, Defendants told investors

that Aclaris's market research estimated that patients were already paying over \$1.2 billion a year for procedures to treat SK.

66. Defendants also emphasized to investors that existing SK treatments were inadequate. Defendants told investors that Aclaris's marketing research showed that patients avoided removing raised SK via cryosurgery, shave excision and/or electrodesiccation and curettage because those treatments were invasive, painful, and could leave scars or skin discoloration.

67. Defendants thus touted ESKATA to investors as a treatment for raised SK that could effectively remove the lesions, was not painful and did not result in skin discoloration. For example, marketing presentations given by Defendant Walker to investors on October 4, 2017 at the Company's "R&D and Investor Event in New York" (the "Investor Event Presentation") and on November 16, 2017 at the Jefferies 2017 London Healthcare Conference in London, UK ("Jefferies Presentation") told investors that the [most common] reasons patients gave for not removing SK lesions were "[r]isk of scarring," "[r]isk of hypopigmentation" (*i.e.*, white spots) "[w]ant to avoid pain or discomfort." In those presentations, Defendant Walker promoted ESKATA as "an appealing concept for SK treatment" because the product presented "minimal discomfort" and "[r]educd risk of pigmentary changes."

68. The press release announcing that the FDA had approved ESKATA similarly touted these purported benefits of the product to investors. For example, the release told investors that Phase 3 clinical trials of ESKATA had shown that "Patients treated with ESKATA were more likely to have all four treated SKs completely cleared after two treatments than patients who received placebo." The press release went on to state that "[t]reatment with ESKATA was generally well tolerated, with the most common side effects being itching,

stinging, crusting, swelling, redness and scaling at the site of application.” In short, in the months leading up to the Class Period, Defendants positioned Aclaris to investors as an effective solution to an existing need in a billion-dollar market that could, by extension, allow Aclaris to reap windfall profits.

69. Based on Defendants’ messaging, the market demonstrated excitement over ESKATA’s commercial potential. For example, in a January 8, 2018 analyst report, a William Blair analyst predicted “peak-year sales” of ESKATA “that could approximate **\$600 million** with **relatively modest penetration assumptions** (about 20%)” (emphasis added). Similarly, in a March 12, 2018 analyst report, a Guggenheim Partners analyst advised investors that the product was likely to realize sales of between \$9.8 million to \$20.7 million in 2018 alone before growing exponentially to **\$576 million** in the United States alone by 2025. Likewise, in an August 3, 2018 analyst report, a Cantor Fitzgerald analyst estimated that ESKATA sales would reach between **\$321 and \$360 million** annually by 2023.

D. Defendants’ ESKATA Marketing Plan

70. Defendants knew that for ESKATA to succeed commercially, they needed to convince patients that ESKATA was effective, did not result in skin discoloration and was not painful. This was particularly true because Defendants knew that patients would be spending their own money on the treatments, which were not covered by insurance. Defendants’ knowledge of this is demonstrated in their statements to investors. For example, in their annual reports on Forms 10-K for the years 2016, 2017 and 2018, Defendants told investors that “[t]he key competitive factors affecting the success of ESKATA for the treatment of raised SKs, are likely to be its efficacy, safety, non-invasiveness, pain profile and ability to be administered by non-physician staff.” Defendants’ marketing presentations promoting ESKATA in October and November 2017 also stated that the top healthcare provider-desired benefits for a topical SK

treatment included “low risk of scarring / depigmentation” and “manageable pain level.” The presentations also quoted a dermatologist as saying “[t]he big thing you always worry about with cosmetic procedures is the outcome—you can get into trouble with pigmentation and scarring, so [low] risk is a big benefit.” A cosmetic dermatologist was quoted as saying, “[m]y immediate reaction is that not having discomfort would be very favorable.” These same presentations also quoted patients as saying that ESKATA “seems to be [a good] option in terms of pain level and damage to the skin,” “it hurts to have [SK lesions] frozen,” “[t]he results look good, and it’s non invasive,” and “I would want no scarring, or discoloration of area and having the pain level at a manageable level.”

71. Defendants implemented a two-phase process for marketing ESKATA. In the first phase, called the ESKATA Early Experience Initiative, sales representatives visited dermatologists and/or other physicians to persuade them to order ESKATA so that the physicians could offer the treatment to patients. The sales representatives provided physicians with brochures and “stand-up banners” advertising ESKATA that physicians could place in office waiting areas. The sales representatives also provided free ESKATA samples to physicians and sat in when the physicians administered the free samples to patients. After the treatments, sales representatives surveyed the physicians and patients on, among other things, a patient’s pain or comfort level and how effectively ESKATA removed raised SK.

72. The second phase of the ESKATA marketing program consisted of direct-to-consumer advertising driving patients to dermatologists and/or other physicians to request treatment for their raised SK with ESKATA. The campaign kicked off with a scripted “interview” segment with a paid ESKATA spokesperson on the daytime talk show “The View.” After the segment aired, Defendants made the segment available online and loaded the segment

onto sales representatives' iPads so that representatives could show it to dermatologists and/or other physicians during sales visits. The segment on The View was accompanied by a print and television advertising campaign.

E. The ESKATA Early Experience Initiative

73. Defendants told investors in marketing presentations that the goal of the ESKATA Early Experience was to “partner with target customers as they gain initial [ESKATA] experience in order to identify best practices and optimize promotions and educational support.” To do this, Defendants would have ESKATA sales representatives meet with hundreds of dermatologists and/or other physicians to introduce them to ESKATA, explain what types of raised SK were appropriate for treatment and train the physicians to apply ESKATA correctly. The sales representative would then sit in on treatments of approximately six patients for each physician's practice using ESKATA, and then ask the physician and patient survey questions after the treatment. The marketing presentations indicated that Defendants were most interested in feedback from physicians on “[l]esion selection, application technique, treatment time, patient management, and patient outcomes,” *i.e.*, efficacy, tolerability and any resulting scarring or skin discoloration.

74. After ESKATA was approved, Defendants hired approximately 50 sales representatives to market the product to physicians. Defendants provided extensive training for its sales representatives, including instructing them on how to identify raised SK that were appropriate for treatment, how to properly apply ESKATA and how to train physicians and their staff to both identify raised SK and apply the product properly. CW3 stated that the training emphasized the risks of severe eye injuries presented by ESKATA and the importance of ensuring that any physician or physician's staff member who actually applied ESKATA avoided

the eye area. CW3 also said that the program did *not* include training concerning the amount or level of pain that patients could expect during treatment.

75. The ESKATA Early Experience Initiative launched in the spring of 2018. When sales representatives sat in on the treatments provided using free samples, however, they were *stunned* to discover that the way the ESKATA worked in practice was shockingly different from what Defendants had described during training. According to CW5, the first time sales representatives actually saw how ESKATA worked in practice was during these testing treatments. He said, “They sold us on this magic pen. We were taking preorders. We had no idea what it would actually be like.” CW9 confirmed that sales representatives did not see how ESKATA actually worked in practice until they were in a customer’s (*i.e.*, a dermatologist’s and/or other physician’s) office watching a physician treat a patient with a free sample. CW9 also described how initially sales representatives were expected to sell the product to physicians (*i.e.*, take pre-orders) before Aclaris could physically deliver the pens, and that customers complained that they had ordered multiple ESKATA pens sight unseen and then could not return the product when it did not work as they expected the product to work.

76. CW3, CW4, CW5, CW8 and CW9, who worked as ESKATA sales representatives, all described the serious pain that patients experienced during ESKATA treatments. CW3 said that after hearing from physicians and patients about pain in ESKATA treatments, he began advising physicians and office staff about the pain associated with the treatment as part of his sales pitch. CW3 said that he would provide this advice by pausing a video he was trained to show physicians and their staff and describe the pain patients could experience during treatment. CW3 provided this advice even though none of Defendants materials or training dealt with pain. CW3 said that he also recommended that physicians and

their staff use “distraction techniques” as a way to try to ameliorate the pain that accompanied the treatment. CW3 said that he never received any training from the company advising of the pain during administration, but chose to begin warning office staff about the pain levels after getting feedback from those who had bought it from him. CW3 had personally witnessed at least one patient refuse to continue ESKATA treatments because it was too painful.

77. CW4 also said that customers (*i.e.*, dermatologists and/or other physicians) told him that ESKATA “hurt people,” left scars and resulted in hyperpigmentation (*i.e.*, skin darkening). CW4 also stated that ESKATA “behaved very differently than the way they [Defendants] presented it. From the way it actually behaved in the field, I never would have taken it to market.”

78. CW5 said that he was shocked to see how ESKATA performed in “real life” compared to how Defendants described the treatment during training. CW5 said that the medicine’s adverse effects were “more severe than anyone was prepared for,” and included on-site reactions, swelling and bubbling as if the skin was burning. CW5 said that he discussed these problems with his peer sales representatives, including during the time when sales representatives were training physicians and non-physician staff on how to use ESKATA (*i.e.*, during the ESKATA Early Experience Initiative), and that the problems were escalated to senior leadership at Aclaris. According to CW5, “[w]e all had the same protocol. We weren’t seeing the same reactions we had been told there would be at all.” CW5 said that senior leadership was “completely defensive” and that the sales representatives’ complaints were blown off.

79. CW8 also said multiple customers reported that ESKATA caused burning and stinging and left large white spots on treated areas. CW8 also said that customers indicated to CW8 that the treatment was not as effective as it had been described. CW8 said that he reported

these complaints through Aclaris's in-house channels for reporting adverse side effects, which escalated reports of the side effects to Aclaris's senior leadership.

80. CW8 summed up the feedback sales representatives received during trials with physicians and patients as, although Defendants were marketing ESKATA "as a safer, easier, non-invasive alternative to competitors," "in reality, it had the same side effects as existing methods of removing SKs but was more expensive." CW4, CW5 and CW13 said that while sales representatives had some success getting physicians to order the product initially, customers would stop ordering the product after they saw it in action and/or patients' responses to it.

81. CW9 said that physicians and patients he worked with had extremely negative experiences with ESKATA, including adverse side effects and limited effectiveness. CW9 said, "I basically lost good working relationships that I had worked to establish since 2009. They trusted me. They bought [ESKATA] believing in me. Some of them wouldn't let me come back into their office." CW9 said that he received complaints about adverse side effects and that the product required many applications to get any results.

82. The CWs' observations of ESKATA in action—namely that it was not effective, was extremely painful, and resulted in skin discoloration—are confirmed by professional reviews of ESKATA and testimonials from ESKATA patients.

83. For example, American Family Physician, a biweekly peer-reviewed medical journal published by the American Academy of Family Physicians, published a review of ESKATA's "Safety, Tolerability, Effectiveness, Price and Simplicity." The review concluded that ESKATA "is *not particularly effective* for removing seborrheic keratosis lesions, and *skin reactions are common* (emphasis added). Long-term minor cosmetic changes may occur,

including hyperpigmentation and hypopigmentation. Hydrogen peroxide 40% topical solution is expensive and requires out-of-pocket payment by patients. Given the high cost of the solution and its potential for adverse effects, other options will be preferred by most patients.”²

84. The CWs’ observations that patients and physicians found that ESKATA was ineffective, painful and left skin discoloration, were also confirmed by patients who received ESKATA treatments and posted comments on those treatments online.

85. The website WebMD.com (“WebMD”) allows its users to post descriptions of their experiences with medications and treatments. WebMD is the most popular source of health information in the United States, and generates revenue primarily through advertising and sponsored content for pharmaceutical, biotech and medical device companies, as well as hospitals, health insurance providers, and lifestyle and wellness brands. WebMD offers a page entitled “User Reviews & Ratings — ESKATA Topical,”³ where visitors to the website post reviews of ESKATA (the “WebMD ESKATA Review Page”).

86. Similarly, the website Drugs.com allows its users to post descriptions of their experiences with medications and treatments. Drugs.com is an online pharmaceutical encyclopedia that provides drug information for consumer and healthcare professionals. As of February 2016, Drugs.com was the sixth most popular internet-based healthcare network, receiving approximately 23 million visitors every month. In fact, the FDA recommends that

² Sandy Robertson, PharmD and John Franko, MD, STEPS: New Drug Reviews, Hydrogen Peroxide 40% (Eskata) for Seborrheic Keratosis, America Family Physician, Nov. 15, 2019, http://www.afp-digital.org/afp/november_15__2019/MobilePagedArticle.action?articleId=1539429#articleId1539429.

³ Available at <https://www.webmd.com/drugs/drugreview-175309-eskata-solution-with-applicator.aspx?drugid=175309&drugname=eskata-solution-with-applicator>.

consumers learn more about drugs and medications by visiting Drugs.com.⁴ Drugs.com also offers a page entitled “User Reviews for ESKATA,”⁵ where visitors to the website post reviews of ESKATA (the “Drugs.com ESKATA Review Page”).

87. On September 22, 2018, one ESKATA patient posted to the WebMD ESKATA Review Page that “I have had three treatments with Eskata for SKs. First, it burns for about 30 minutes when applied. Then the areas turn white for a couple of hours, so if you have them on your face, you have to hide. Worst of all, it’s pretty ineffective. With a thin SK, it usually comes off in one treatment, but with thicker ones, it seems just to burn off the top layer. I’ve had the same SKs that are still there after 3 treatments. I have to go back for a 4th treatment on the SAME SKs. They are partially gone, but not completely.”

88. A year later, on September 13, 2019, another ESKATA patient wrote on the WebMD ESKATA Review Page, “‘Stinging’ is an understatement. This is a chemical burn! And the pain is what you might expect from a chemical burn that goes beneath the outer surface of the skin. Don’t know yet if my treatment will be effective as it was only 4 days ago, but the spots on my face are still white and sore and the spots on my lower chest are red and oozing. I won’t be going back for further treatment.”

89. On September 21, 2019, a third user wrote on the WebMD ESKATA Review Page, “[a]fter 15 weeks and 3 different, periodic treatments of ESKATA by my dermatologist for 6 dark spots on my face, it proved to be very ineffective. At best, it lightened my dark spots no more than a negligible 5-10%. I would NOT recommend ESKATA to anyone. Not only is it disappointingly ineffective, it’s also very expensive.”

⁴ FDA, *How can I stay better informed about drugs? Is there a reliable website FDA recommends?*, FDA.gov (last visited Jan. 24, 2020), <https://www.fda.gov/drugs/questions-answers/how-can-i-stay-better-informed-about-drugs-there-reliable-website-fda-recommends>

⁵ Available at <https://www.drugs.com/comments/hydrogen-peroxide-topical/eskata.html>.

90. The Drugs.com ESKATA Review Page contains nine consumer reviews of ESKATA, all of which criticize the drug as ineffective, extremely painful and/or expensive. For example, on the day the ESKATA became commercially available, May 7, 2018, a patient wrote on the Drugs.com ESKATA Review Page that “[a]fter one treatment none of my SK was gone. Seeing the doctor tomorrow and expect she will recommend another treatment on same spots for another \$200. Very disappointed.”

91. In September 2018, another patient wrote on the Drugs.com ESKATA Review Page, “[h]ad treatment on face. Burned a lot all over, could not open my eyes for about 30 minutes. worst experience of my life. I don't recommend this product to anyone.”

92. In January 2019, a third reviewer wrote on the Drugs.com ESKATA Review Page, “Stay away from Eskate [SIC] treatment. The doctor and I were not impress [SIC] with the treatment none of the age spots disappear. Burns like hell, made my face look like someone through hot oil on it. It’s not covered by insurance, cost \$200.”

93. In June 2019, another user wrote on the Drugs.com ESKATA Review Page, “It has been over 100 days and my spots are not gone. It just burned a lot and left a red ring around each one. The ring is fading but still can be seen after 100 days. Waste of money.”

94. Finally, [i]n September 2019, a patient wrote on the Drugs.com ESKATA Review Page, “I chose this treatment because it was supposed to be painless. Was told to expect ‘some stinging during treatment.’ That was an understatement! It was an extremely painful experience for me that continued for several hours, of such severity that I thought I would vomit.”

95. CW7 said that the problems with ESKATA, Aclaris’s only product at the time, were well-known throughout the Company, and specifically by Defendants Walker, Ruffo and Ali-Jackson, including the product’s limited effectiveness and more intense side effects, like pain

and skin discoloration. CW7 said that, “The [lack of] sales were questioned and everybody knew about it.”

96. CW8 stated that sales representatives discussed the incidence of pain, white spots, and efficacy, as well as the product’s failure to remove raised SK, during the sales representatives’ regular calls and meetings. Senior Aclaris executives attended these calls and reported those incidences up to the highest levels of the Company. CW5 and CW10 also said that sales representatives discussed the problems with ESKATA on multiple occasions and escalated them to executives at Aclaris. CW5 said that Company executives simply dismissed these concerns.

97. The Individual Defendants also had actual knowledge of ESKATA’s limited effectiveness, pain and resulting skin discoloration based on the Company’s protocol for reporting adverse effects. Any adverse effect was reported to a safety officer, who would fill out required paperwork that would reported to the Company’s senior leadership. According to multiple CWs, Aclaris was closely managed by its senior leadership, including the Individual Defendants. CW2 also stated that the Individual Defendants were focused on ESKATA because it was the Company’s main product during the Class Period, especially during the ESKATA Early Experience Initiative and the first six months that ESKATA was marketed. Accordingly, these adverse events were reported to Defendants Walker, Ruffo, Ali-Jackson and Fair, who thus had actual notice of the pain, limited effectiveness and skin discoloration plaguing patients treated with ESKATA.

98. CW9 said that as a high-performing sales representative, he was placed on an executive sales team at Aclaris that was formed to help improve sales. The executive sales team met at Aclaris’s headquarters approximately six months after ESKATA entered the marketplace,

between August and October 2018. The members of the executive sales team discussed the complaints sales representatives had received from physicians and patients about adverse side effects and complaints that ESKATA was not effective. CW9 had heard complaints from customers that ESKATA was ineffective because it took many *more* applications to achieve any results than the physicians had been told when they were sold the product. CW9 said that Defendants Walker and Fair attended this meeting, along with other members of the Company's senior leadership.

99. Defendants officially launched ESKATA the first week of May 2018. Although Defendants had actual knowledge that ESKATA treatments were limited in effectiveness, extremely painful and left skin discoloration, Defendants concealed these facts and misrepresented ESKATA to investors. For example, on the first day of the Class Period, May 8, 2018, Defendants held an earnings call after the markets closed to report the Company's performance for the first quarter of 2018. On that call, Defendants outright lied, saying "[t]he patients *enjoy* [ESKATA], seems to be a *comfortable* treatment" (emphasis added). These statements were false and misleading because Defendants knew from reports from sales representatives that patients found ESKATA treatments painful, were upset by the skin discolorations that persisted after treatments and were dissatisfied with ESKATA's failure to remove raised SK. On the same call, Defendants also misrepresented the results of physician and patient surveys that sales representatives had taken during the ESKATA Early Experience Initiative, telling investors that "[t]he patient feedback is also very encouraging" and that an overwhelming majority of patients found the treatment easy, "were comfortable enough with their appearance to go out socially," and would recommend ESKATA to their friends.

100. In the days following these disclosures, Aclaris's share price soared 7.9% from \$18.01 per share to \$19.44 per share. Defendants made substantively identical false and misleading statements on an earnings call three months later that disclosed the Company's performance for the second quarter of 2018. In the aftermath of these disclosures, Aclaris's share price briefly rose from 0.5% from \$17.37 per share to \$17.46 per share.

101. Unsurprisingly, given physicians' and patients' complaints to sales representatives, ESKATA's sales started poorly and then collapsed during the Class Period, from \$1.5 million in sales in the first three months the product was available in the second quarter of 2018 to only \$300,000 in sales in the last quarter of the Class Period, the second quarter of 2019. Indeed, throughout the Class Period ESKATA sold poorly: After reported net sales of ESKATA of \$1.5 million for the second quarter of 2018, Defendants reported net sales of ESKATA of \$500,000 in the third quarter of 2018, \$800,000 in the fourth quarter of 2018, \$100,000 in the first quarter of 2019, and \$300,000 in the second quarter of 2019.

102. During this time, however, Defendants never disclosed to the public that ESKATA's sales were poor because of the product's limited effectiveness, pain and persistent skin discolorations. Instead, on an earnings call on November 6, 2018, Defendants claimed that ESKATA's sales were falling because the product *worked too well*, telling investors that the product was "actually clearing lesions a ***lot quicker, one to two times***," i.e., in only one or two physicians' visits. This statement was false because Defendants Walker and Fair, among other senior Aclaris leadership, had attended an "executive sales team" meeting between August and October 2018 where the sales representatives discussed complaints from physicians and patients about ESKATA's side effects and ineffectiveness, including that ESKATA took many *more* applications to achieve any results than the physicians had been told when they were sold the

product. In response to this disclosure, Aclaris's share price briefly rose 2.2% to \$12.01 per share.

103. In January 2019, out of sheer desperation, Defendants launched a "corrective action plan" to try to generate positive patient experiences with ESKATA by directing sales representatives to offer to retrain physicians and their staffs on how to apply ESKATA in the hopes that additional training would make the treatment less painful, more effective, and not result in skin discoloration. The Individual Defendants had personal knowledge of the existence and contents of the corrective action plan, and, according to CW7, who worked to provide more on ESKATA that could be shared with physicians as part of the plan, the fact that Aclaris was resorting to a corrective action plan to boost sales was known through the Company. Defendants never publicly disclosed this corrective action campaign, which was an abject failure. Indeed, CW5 said that some physicians simply refused the retraining. Nor did Defendants ever disclose to investors that ESKATA's commercial failure was because it was ineffective, extremely painful and left skin discoloration.

F. The ESKATA DTC Campaign

104. At the same time Defendants were misleading investors about patients' reactions to ESKATA and ESKATA's declining sales, Defendants also concealed from investors that Defendants had implemented a scheme to use a direct-to-consumer marketing campaign (the "DTC campaign") that materially misled patients about ESKATA's risks and effectiveness in violation of federal law.

105. The Federal Food, Drug and Cosmetics Act ("FFDCA") prohibits making false or misleading claims and/or representations about the risks associated with and the efficacy of pharmaceuticals and medical devices. For example, it is a violation of the Federal Food, Drug and Cosmetic Act to "introduce[e] or deliver[]" for introduction into interstate commerce of any

food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.” *See* 21 U.S.C. 331(a). A drug is “misbranded” if, among other things, its advertising is misleading. *See id.* § 352(b), (c), (n). In direct contravention of the FDCA, Defendants used marketing materials in their direct-to-consumer advertising campaign for ESKATA that failed to disclose serious risks associated with ESKATA, created misleading impressions about ESKATA’s common adverse reactions and/or misleadingly represented that patients treated with ESKATA would experience complete clearance of all treated raised SK.

106. For example, Defendants launched the DTC campaign with a scripted segment that aired on the daytime talk show “The View” on September 19, 2018. “The View” is an hour-long talk show airing on the ABC Television Network since August 1997. The View is “hosted” by a panel of women who discuss current events, including sociopolitical and entertainment news. In addition to these conversational segments, the panel also interviews celebrities and politicians and provides diet, fashion, health and relationship tips. The View is taped in a studio located at 57 West 66th Street, New York, New York.

107. Episodes of The View also regularly include staged “interviews” of paid spokespeople for healthcare and beauty products, including pharmaceutical products. Although these segments of The View are presented to audiences as if they are live interviews that are part of the day’s program, they are, in fact, paid advertisements.

108. The staged interview segment promoting ESKATA lasted approximately two minutes. The segment’s script was edited, reviewed and approved by the Individual Defendants. In the segment, host Abigail “Abby” Huntsman (“Ms. Huntsman”) “interviewed” dermatologist Dr. Doris Day (“Dr. Day”), a paid Aclaris spokesperson, about a new treatment for raised SK.

Dr. Day described raised SK and touted ESKATA as a way to completely remove the lesions without residual skin discoloration or scarring.

109. During the segment, after Dr. Day described raised SK, Ms. Huntsman asked, “You mention [raised SK are] on your face, you want to get rid of them, what is the answer?” Dr. Day responded, “so there is a new in-office treatment called ESKATA. ESKATA is a topical 40% hydrogen peroxide solution that’s applied right to the spots, the raised seborrheic keratosis, right on the spots And, *typically in one or two treatments the lesions go away, they resolve, and that’s the end of it*” (emphasis added).

110. Dr. Day’s claim was immediately followed by two sets of three side-by-side “before-and-after” images of two patients with raised SK who purportedly had all of their lesions completely removed within 106 days of treatment with ESKATA without scarring. Each set of images was labeled “BEFORE,” at “3 WEEKS” and on “DAY 106 (Final Result).” The first set of images presented a patient with *over 10 raised SK* and showed that all of the lesions were completely removed without skin discoloration. The second set of images presented a patient with fewer raised SK, but also indicated that all the raised SK were completely removed without skin discoloration.

111. As these before and after images were shown, Dr. Day told viewers, “so you can see from the before and afters what it [treatment with ESKATA] looks like.” Ms. Huntsman then asked, “Does it burn as you’re doing it?” In response, Dr. Day demurred, “[i]t can sting as you apply it.” The images, which were large, dwarfed a disclaimer in a small font stating that “18% of patients experienced clearance of 3 out of 4 raised SKs treated with ESKATA vs. 0% with vehicle (Day 106 end of study),” “[m]ost common side effects are itching, stinging, crusting, swelling, redness and scaling” and “[a]ctual patient. Individual results may vary.”

112. The segment concluded with Ms. Huntsman suggesting that ESKATA can completely remove raised SK. Ms. Huntsmen stated that “I am one of many I think that have their own insecurities about the spots as we age, we get older, good to know though it is not dangerous and *there is a way to get rid of them*” (emphasis added).

113. The segment contained multiple flagrant violations of the FFDCA. First, the video *entirely omitted* the two serious warnings that the FDA had required ESKATA place on its label. Neither Ms. Huntsman nor Dr. Day mentioned the risk of severe eye damage in the video. This omission was especially misleading because most ESKATA treatments involve applying the product to a patient’s face (*i.e.*, near a patient’s eyes) given that raised SK commonly appear on a patient’s face. In fact, on March 29, 2018, as the ESKATA Early Experience Initiative was under way, the FDA’s Office of Prescription Drug Promotion (“OPDP”) sent Defendants the March 2018 Letter, which recommended that Aclaris “revise proposed presentations [for ESKATA] so that they did not omit material information regarding the risks associated with ESKATA or otherwise misrepresent important risk information.” In other words, the OPDP expressly told Defendants to make sure that their advertising materials warned of the risk of severe eye damage.

114. In addition, neither Ms. Huntsman nor Dr. Day informed viewers that ESKATA presented risks of severe skin reactions including “erosion, ulceration, vesiculation and scarring.” Instead, the video only briefly displayed text stating that the “most common side effects are itching, stinging, crusting, swelling, redness and scaling.” In addition, (i) the before and after photos, (ii) Dr. Day’s statement to viewers that “*typically in one or two treatments the lesions go away, they resolve, and that’s the end of it*” and (iii) Dr. Day’s statement that the treatment may only “sting,” plainly conveyed to viewers that ESKATA completely removed raised SK,

was not painful and did not result in skin discoloration. Dr. Day's statement, along with the before and after photos, strongly suggested that these patients could remove *all* of their lesions with ESKATA. Defendants knew, however, that this result was virtually impossible.

115. Defendants also had Dr. Day make these flagrantly violative representations intentionally, or at the very least recklessly, because the Individual Defendants were directly involved in reviewing, editing and/or approving the segment's script. According to CW7, Aclaris's director of medical information, who reported directly to CW7, told him that the script for The View segment was drafted and revised through several "highly contentious" Promotions, Regulatory and Compliance ("PRC") meetings attended by Defendant Ali-Jackson where the claims about how to market ESKATA give its limited effectiveness and side effects were debated. In addition, CW7 said he learned from the then-director of medical information that Defendant Ali-Jackson was personally editing the segment's script "up until the last minute." CW3 and CW7 also said that Defendant Ali-Jackson, along with several other members of Aclaris's senior leadership team, were on-site when the segment was taped. Finally, CW7 stated that he learned from Aclaris's then-director of medical information the script for The View segment was escalated to Defendants Walker, Ruffo, Ali-Jackson, Fair and other senior leadership after it was debated in PRC meetings. In short, the Individual Defendants reviewed, edited and approved the script for the segment promoting ESKATA on The View.

116. Rather than retape the segment so that it was consistent with federal law and did not misrepresent ESKATA's effectiveness and omit its serious risks, Defendants doubled down on the misleading statements in the segment by making sure that as many patients and investors saw it. Shortly after the interview aired, Defendants made the video available on the internet on the Facebook page and LinkedIn page advertising ESKATA. According to CW7, Defendant

Ali-Jackson's own administrative assistant posted the video to these websites at Ali-Jackson's instruction. The video was also posted to the website YouTube.com as well on a "channel" devoted to episodes of The View.⁶ Finally, Defendants loaded the segment on to iPads that sales representatives brought to meetings with physicians and patients.

117. Defendant's entire DTC campaign misrepresented ESKATA's effectiveness in the same way that the segment on The View misrepresented the product's effectiveness because Defendants made before-and-after images the focal point of their ESKATA advertising.

118. For example, a 60-second television commercial for ESKATA included both sets of before-and-after photographs that appeared in the segment on The View. Similarly, a promotional brochure for ESKATA that physicians could distribute to patients also used before and after photos purporting to show raised SK that ESKATA completely removed.

119. "Stand-up banners" promoting ESKATA that Defendants' sales representatives gave to physicians to place in waiting rooms also used one of the sets of before-and-after photographs from the segment that was shown during the segment on The View and *entirely omitted* the disclaimer that "18% of patients who experienced clearance of 3 of 4 raised SKs treated with ESKATA as compared to 0% with vehicle (Day 106 end of study)." In addition, the stand-up banner included a set of images presenting a patient with **over ten** raised SK that purported to show that **all ten** of the lesions were completely removed without scarring.

120. Finally, print advertisements for ESKATA also used the before and after images from the segment on The View of the patient who purportedly had over 10 raised SK completely removed using ESKATA without any residual skin discoloration. These advertisements were

⁶ Although these pages on Facebook, LinkedIn and YouTube have been taken down, the video nevertheless remains available on Facebook. See <https://www.facebook.com/watch/?v=2610721368968132> (last visited January 24, 2020).

especially misleading because one-third of the 83 million patients in the United States with raised SK have more than 15 lesions. Dr. Day's statement, along with the before and after photos, strongly suggested that these patients could remove *all* of these lesions with ESKATA. Defendants knew, however, that this result was virtually impossible.

121. Defendants knew that the advertisements in the DTC campaign misrepresented ESKATA's effectiveness because federal regulators had repeatedly warned Defendants about marketing materials that omitted or misrepresented material information regarding ESKATA's risks and overstated ESKATA's effectiveness.

122. For example, on April 29, 2015, as the Company was preparing to go public, the SEC sent Defendant Ali-Jackson a letter with comments on Aclaris's draft registration statement on Form S-1. The SEC's April 29, 2015 letter directed Aclaris to remove before and after photos from its registration statement because "it is unclear whether the examples shown on the pages are fair representations of the observed outcomes of your trials," "[n]or is it clear how the 'before' and 'after' photographs depicted compare to photographs of the larger spectrum of patients." A month later, on May 14, 2015, Aclaris's outside counsel responded to the SEC's April 29, 2015 comment letter by confirming that the photos had been removed. Both Defendant Walker and Ms. Kamil Ali-Jackson were copied on the letter. When Aclaris launched its initial public offering, its offering documents did not include the before and after photographs.

123. Similarly, on March 29, 2018, as the ESKATA Early Experience Initiative was under way, the FDA's Office of Prescription Drug Promotion ("OPDP") sent Defendants a letter recommending that Aclaris "revise proposed presentations [for ESKATA] so that they did not omit material information regarding the risks associated with ESKATA or otherwise misrepresent important risk information" and also recommending that "Aclaris revise proposed

presentations so that they did not overstate the efficacy of ESKATA.” In other words, the FDA specifically instructed Defendants to take care to ensure that ESKATA’s effectiveness at removing raised SK was presented accurately and that risks associated with the treatment, which included severe eye injury, pain and scarring, were not concealed.

124. Defendants had actual notice of the letter because, according to CW1, Defendants Walker, Ruffo and Ali-Jackson always received communications from the FDA and were copied on communications from the Company to the FDA. CW7 also confirmed that Defendants Walker, Ruffo and Ali-Jackson would have reviewed all correspondence from and approved all correspondence to the FDA. CW2 stated that since ESKATA was central to Aclaris’s operations, the Company’s senior leadership team, including the Individual Defendants, were involved in all aspects of bringing ESKATA to market and would have been aware of the substance of any communications to or from the FDA. Although Defendants had actual knowledge of the March 2018 Letter, they never disclosed the OPDP’s warning to investors.

125. Defendants also had actual knowledge, or at the very least were reckless in disregarding, that their DTC campaign misrepresented ESKATA’s risks and efficacy. For example, CW7, Aclaris’s former Executive Director of Medical Affairs, said concerns were repeatedly raised that marketing materials and other publications promoting ESKATA were misrepresenting the product’s safety and effectiveness. CW7 stated that concerns about how the Company’s marketing materials and other publications were making misleading statements about ESKATA’s safety and effectiveness were debated at twice-weekly PRC meetings. According to CW7, Defendant Ali-Jackson attended every PRC meeting and heard all of the concerns about statements Aclaris was making or planning to make in marketing materials, which were raised by, among others, CW7 and CW7’s staff, including Aclaris’s director of medical information,

who reported to CW7. CW7 that all these concerns were documented, and that it was ultimately the legal team, and Defendant Ali-Jackson, who settled the disputes that were not escalated to Defendants Walker, Ruffo and Fair.

126. CW7 said that he personally attended many sessions with Defendants Ali-Jackson, Walker, Ruffo and Fair that occurred because concerns about misleading claims about ESKATA's effectiveness and risks that had been raised during PRC meetings were being "escalated" to Walker, Ruffo and Fair. CW7 also said that he personally voiced concerns at PRC meetings that were escalated to the Individual Defendants.

127. CW7 also said that he expressed concerns at the PRC meetings, while Defendant Ali-Jackson was in attendance, that marketing materials that the Company was planning on using were not consistent with the guidance that the Company had received from the FDA's OPDP in the March 2018 Letter. According to CW7, the letter included specific guidance on the types of claims that Aclaris should make in its advertising for ESKATA. CW7 said that he would reference the language in that letter when arguing that ESKATA's advertising was misleading, but that he was told that the Company had decided to take a bigger risk and that the Individual Defendants (and other senior managers) "want to look at (the data) this way.," *i.e.*, not make any changes to the statements in their marketing materials. CW7 also said that his supervisor, Aclaris's then-medical director Esther Estes, who reported directly to Defendant Walker, told him to stop raising concerns because "dermatology pharmaceutical companies do things differently."

128. Although Defendants knew that their DTC advertising campaign misrepresented the risks and efficacy of ESKATA in violation of federal law, Defendants never disclosed this fact to investors. Instead, as described in Sections VI.D and VI.E below, Defendants repeatedly

touted to investors during the Class Period the effectiveness of their advertising campaign in generating interest in ESKATA.

VI. MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

129. Throughout the Class Period, Defendants disseminated materially false and misleading statements and failed to disclose material adverse facts about Aclaris’s business, operations, and prospects. Specifically, Defendants (i) falsely and misleadingly told investors that patients “enjoyed” ESKATA, found it “comfortable,” and that the treatment “works” and “resolves well,” (ii) disclosed the results of “surveys” that misleadingly suggested that ESKATA was effective and well-tolerated by patients, when in fact patients and physicians found the treatment painful and limited in effectiveness, (iii) falsely attributed ESKATA’s poor sales to the fact that patients needed fewer treatments than expected to remove their raised SK, (iv) falsely and misleadingly touted the Company’s DTC advertising campaign while failing to disclose that the campaign was designed to mislead patients as to the risks and effectiveness of ESKATA in violation of the FFDCA, and (v) failed to disclose the risk of regulatory action created by Defendants’ violations of the FFDCA.

A. Defendants’ Descriptions of Patients’ Reactions to ESKATA Were Materially Misleading

130. During the Class Period, Defendants misrepresented to investors that ESKATA was well-tolerated and effective. Defendants’ statements also concealed the risk that ESKATA could not be successfully commercialized since it was limited in effectiveness, painful, left skin discoloration and thus was no better than existing alternatives.

131. On May 3, 2018, Defendants held a conference call to disclose the Company’s financial performance for the first quarter of 2018 (the “Q1 2018 Call”). Defendants Walker, Ruffo, Ali-Jackson and Fair participated in the Q1 2018 Call. During the Q1 2018 Call, a Cantor

Fitzgerald analyst asked Defendants, “on ESKATA, how does the efficacy of the product in your limited sort of trials of product right now compared to what you saw in the clinical trial setting?” Defendant Fair responded, “[t]he patients *enjoy* it, seems to be a *comfortable* treatment” (emphasis added).

132. Three months later, on August 3, 2018, Aclaris held a conference call with analysts to disclose the Company’s financial performance for the second quarter of 2018 (the “Q2 2018 Call”). Defendants Walker, Ruffo, Ali-Jackson and Fair participated in the Q2 2018 Call. During the Q2 2018 Call, Defendant Fair told attendees that “*we are seeing favorable patient outcomes for the product.*” Later in the Q2 2018 Call, a Jefferies analyst asked “maybe give us some—an example of what sort of pushback you’re getting from some of the doctors and conversely maybe anecdote on how much they’re willing to embrace [ESKATA]?” Defendant Fair responded by telling the analyst, among other things, that “*the product really works* and I’m pleased. I mean that sets us up really well for the long term. But, *this product really works It’s a comfortable treatment, it’s easy, it’s quick, and the patients look good, the next day it resolves well*, you don’t have a lot of the edema and crusting and bleeding that you do with some of the other procedures they’re currently using” (emphasis added).

133. Defendants’ statements in paragraphs 131–132 above, which were not qualified, corrected or objected to by any of the other Individual Defendants at the time they were made, misled investors that patients “enjoyed” ESKATA, found it “comfortable,” and that the treatment “works” and “resolves well” and thus that the product was well-tolerated and effective. These statements were false and misleading because, as described by CW3, CW4, CW5, CW8 and CW9, physicians and patients had repeatedly complained to ESKATA sales representatives that ESKATA was painful, did not completely remove lesions, and left persistent skin discolorations.

These statements also concealed the risk that ESKATA could not be successfully commercialized since it was limited in effectiveness, painful, left skin discoloration and thus was no better than existing alternatives. Defendants knew from reports from sales representatives that patients found ESKATA treatments painful, were upset by the skin discolorations that persisted after treatments and were dissatisfied with ESKATA's failure to remove raised SK.

B. Defendants' Statements Concerning the ESKATA Early Experience Initiative Were Materially Misleading

134. During the Class Period, Defendants disclosed to investors misleading results of results of "surveys" administered by Aclaris sales representatives as part of the "ESKATA Early Experience Initiative." These statements misrepresented to investors that ESKATA was well-tolerated and effective. These statements also concealed the risk that ESKATA could not be successfully commercialized since it was limited in effectiveness, extremely painful, left skin discoloration and thus was no better than existing alternatives.

135. During the Q1 2018 Call, Defendant Fair claimed that, in response to surveys administered by Aclaris sales representatives as part of the ESKATA Early Experience Initiative, among other things, "80% of physicians indicated that applying ESKATA is easy or extremely easy, physicians indicated that it only takes 10 minutes on average to apply ESKATA, and 67% of physicians indicated that they would be comfortable delegating the application of a ESKATA to another trained HCP in the office." In addition, Fair said that "[t]he patient feedback is also *very encouraging*. Over 96% of patients said that the ESKATA treatment application was easy, and completed in a reasonable amount of time, 81% of patients indicated that the day after treatment, they were comfortable enough with their appearance to go out socially. And 86% said that they would recommend ESKATA treatment to their friends" (emphasis added).

136. Three months later, during the Q2 2018 Call, Defendant Fair stated that, “Feedback from the Early Experience Initiative *supports that ESKATA provides an excellent treatment option for patients* with raised SK, and one that is easy to administer and delegate within practice” (emphasis added). Defendant Fair also provided an update on the results of “surveys” administered by Aclaris sales representatives as part of the ESKATA Early Experience Initiative. Defendant Fair claimed that “Over 80% of physicians indicated that applying ESKATA is easy or extremely easy. 67% of physicians indicated that they would be comfortable delegating the application of ESKATA to another trained HCP in the office. An additional 15% will determine delegation once they've had more hands-on experience with the product.” Fair continued, [o]ver 90% of patients said that ESKATA treatment application was easy and was completed in a reasonable amount of time. Over 80% of patients indicated that the day after treatment they were comfortable enough with their appearance to go out socially. 85% of patients said that they would recommend ESKATA treatment to their friends and, if previously treated, over 90% of patients said that they would recommend ESKATA over prior treatment methods.”

137. Defendants’ statements in paragraphs 135–36 above, which were not qualified, corrected or objected to by any of the other Individual Defendants at the time they were made, when read collectively, created a misleading impression in investors that the product was well-tolerated and effective. By making the statements discussed in paragraphs 135–36 above, Defendants were required to disclose all material facts necessary to make those statements not misleading. Defendants breached this duty by failing to disclose that, as described by CW3, CW4, CW5, CW8 and CW9, physicians and patients had repeatedly complained to ESKATA sales representatives that ESKATA was painful, did not completely remove lesions, and left

persistent skin discolorations. These statements also concealed the risk that ESKATA could not be successfully commercialized since it was limited in effectiveness, painful, left skin discoloration and thus was no better than existing alternatives. Defendants knew from reports from sales representatives that patients found ESKATA treatments painful, were upset by the skin discolorations that persisted after treatments and were dissatisfied with ESKATA's failure to remove raised SK.

C. Defendants' Materially Misled Investors as to the Cause of ESKATA's Poor Sales

138. Defendants never disclosed to the public that ESKATA's sales were poor because ESKATA was limited in effectiveness, extremely painful and left skin discolorations. Instead, Defendants misrepresented to investors that ESKATA's sales poor because the product was working *too well*.

139. On November 6, 2018, Defendants held a conference call to disclose the Company's financial performance for the third quarter of 2018 (the "Q3 2018 Call"). Defendants Walker, Ruffo, Ali-Jackson and Fair participated in the Q3 2018 Call. On the Q3 2018 Call, Defendant Walker disclosed that net sales of ESKATA for the third quarter of 2018 were \$500,000. Later in the call, in response to a question from a Guggenheim securities analyst, "I think in the past you have mentioned that the doctor experience with ESKATA seems to be progressing. So, is there a change in the physician experience versus the initial stages of the launch that you are seeing?" Walker assured the analyst that "***I think what we're finding is that we're actually clearing lesions a lot quicker, one to two times.*** And that's kind of good and bad. ***I think we're getting a little bit more robust response, but sometimes that results in a little bit of a brisker reaction.***" (emphasis added).

140. Defendant Walker's statement in paragraph 139 above, which was not qualified, corrected or objected to by any of the other Individual Defendants, was false and misleading

because as described by CW3, CW4, CW5, CW8 and CW9, Defendants knew from reports from sales representatives that ESKATA's lagging sales were because the treatment was limited in effectiveness, painful and left persistent skin discolorations. Defendants also knew this was false, because they had attended a meeting of an "executive sales team" of high-performing sales representatives between August and October 2018 where the sales representatives discussed, among other things, the complaints sales representatives had received from physicians and patients about ESKATA's adverse side effects and ineffectiveness, including that ESKATA took many *more* applications to achieve any results than what dermatologists and/or other physicians had been told when they were sold the product. These statements also concealed the risk that ESKATA was not commercially viable.

D. Defendants Failed to Disclose to Investors that they Were Using Marketing Materials that Made False or Misleading Claims About ESKATA's Efficacy

141. During the Class Period, Defendants touted the progress of Aclaris's DTC campaign as raising awareness and driving patients to dermatologists and/or other physicians for ESKATA treatments. These statements were materially false and/or misleading, however, because Defendants did not disclose that their advertising campaign was raising aware and driving patients to physicians by misrepresenting the risks and efficacy of the treatment in violation of the FFDCA.

142. During the Q2 2018 Call, Defendant Fair told investors that "[w]ith regards to DTC, we have filmed the ESKATA TV commercial and plan to air the commercial beginning in October. ESKATA TV commercial is part of a comprehensive consumer campaign that includes both print and digital media, with the goal of driving SK awareness and treatment with ESKATA. *Our consumer campaign will encourage patients to see their dermatologist* and/or go to eskata.com to find a provider near them."

143. Also during the Q2 2018 Call, in response to a question from a Cantor Fitzgerald analyst, Defendant Fair touted the success of the Company's marketing campaign for ESKATA, boasting, "right now, we're focused on driving clinical integration between now and DTC in October. ***We think we're in a good place. I think we'll be in a very good place come the time we activate DTC*** and I think that's when you'll start seeing it really start picking up."

144. During the Q3 2018 Call, Defendant Fair touted to investors how the Company's segment on "The View" advertised ESKATA to consumers. Defendant Fair stated that, "[w]e ***believe our DTC and PR efforts, such as our most recent spot on The View***, will also help drive interest as patients are directed to the Find a Doctor page on the ESKATA website." Later in the call, in response to a question from a Jefferies analyst, Defendant Fair said, "we've seen a big spike in, obviously, in the website traffic results over the course of October, ***saw a big spike with The View and then we've seen that big spike continue to grow in the month of October***. That's a good sign."

145. By making the statements discussed in paragraphs 142–44 above, Defendants boasted to investors that their marketing program for ESKATA drove physicians to offer the treatment and patients to try the treatment, but failed to disclose to investors that the materials used to drive physician and patient interest were misleading regarding ESKATA's effectiveness and, in some cases, omitted the treatment's serious health risks. By making these statements, Defendants were required to disclose all material facts necessary to make those statements not misleading. Defendants breached this duty by failing to disclose that their DTC campaign was misrepresenting the risks and efficacy of ESKATA in violation of the FFDCA in an effort to drive patients to ask physicians for the treatment. The statements also concealed the risk that

ESKATA was not commercially viable and could only be effectively marketed using materials that misrepresented ESKATA's risks and efficacy.

E. Defendants Misrepresented the Company's Risks Related to Its Failure to Comply with Regulatory Requirements

146. Defendants' failure to disclose that their DTC campaign was misleading patients as to the risks and efficacy of ESKATA in violation of the FFDCA also rendered certain of Aclaris's risk factors contained in annual and quarterly reports on Forms 10-K and 10-Q that the Company filed with the SEC misleading because the risk factors misrepresented and/or failed to disclose that Aclaris was already not complying with regulatory requirements, namely the branding requirements of the FFDCA.

147. The 2017 10-K contained a boilerplate "risk factor" generically advising investors that "ESKATA, or any drug candidate for which we obtain marketing approval, could be subject to post-marketing restrictions or recall or withdrawal from the market, and *we may be subject to penalties if we fail to comply with regulatory requirements* or if we experience unanticipated problems with our drug candidates, when and if any of them are approved" (emphasis added). The risk factor went on to state that "[v]iolations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws."

148. The Q2 and Q3 10-Qs stated that Aclaris's "risk factors have not changed materially from those described in 'Part I, Item 1A. Risk Factors' of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018.'" Accordingly, the Q2 and Q3 2018 10-Qs incorporated the boilerplate risk factor regarding Aclaris's regulatory compliance from the 2017 10-K.

149. The 2018 10-K contained the same boilerplate “risk factor” advising investors that “ESKATA, or any drug candidate for which we obtain marketing approval, could be subject to post-marketing restrictions or recall or withdrawal from the market, and *we may be subject to penalties if we fail to comply with regulatory requirements* or if we experience unanticipated problems with our drug candidates, when and if any of them are approved” (emphasis added). The risk factor went on to state that “[v]iolations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.”

150. The Q1 and Q2 2019 10-Qs also stated that Aclaris’s “risk factors have not changed materially from those described in ‘Part I, Item 1A. Risk Factors’ of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 18, 2019.” Accordingly, the Q1 and Q2 2019 10-Qs incorporated the boilerplate risk factor Aclaris’s regulatory compliance from the 2017 10-K.

151. By making the statements discussed in paragraphs 147–50 above, Defendants were required to disclose all material facts necessary to make those statements not misleading. Defendants breached this duty by failing to disclose that Defendants’ DTC campaign was misrepresenting the risks and efficacy of the treatment in violation of the FFDCA in an effort to drive patients to ask physicians for ESKATA. Investors were thus not aware of the material risk to their investment caused by Defendants’ failure to comply with regulatory requirements, namely the branding requirements of the FFDCA.

F. Defendants Walker and Ruffo’s Certifications Attached as Exhibits to Aclaris’s Quarterly and Annual Reports Were False and Misleading

152. Appended as exhibits to the Company’s 2018 10-K were signed certifications pursuant to the Section 302 of the Sarbanes-Oxley Act of 2002, in which Defendants Walker and

Ruffo each certified that he had “reviewed the annual report on Form 10-K of Aclaris Therapeutics, Inc. [and] . . . [b]ased on my knowledge, [the] report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.”

153. Also appended to the Company’s 2018 10-K was a signed certification pursuant to 18 U.S.C. § 1350 in which Defendants Walker and Ruffo certified that “to the best of [their] knowledge: (1) [The 2018 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and (2) The information contained in [the 2018 10-K] fairly presents, in all material respects, the financial condition and result of operations of the Company.”

154. Appended as exhibits to the Company’s Q1 2018 10-Q, Q2 2018 10-Q, Q3 2018 10-Q, Q1 2019 10-Q and Q2 2019 10-Q (the “Class Period 10-Qs”) were signed certifications pursuant to the Section 302 of the Sarbanes-Oxley Act of 2002, in which Defendants Walker and Ruffo each certified that he had “reviewed this Quarterly Report on Form 10-Q of Aclaris Therapeutics, Inc. [and] . . . [b]ased on my knowledge, [the] report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.”

155. Also appended to the Class Period 10-Qs were signed certifications pursuant to 18 U.S.C. § 1350 in which Defendants Merlo and Denton certified that “to the best of [their] knowledge,” each Class Period 10-Q “fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and . . . [t]he information contained in [each Class Period 10-

Q] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

156. Each of the above statements excerpted from the exhibits to the Company’s 2018 10-K and each Class Period 10-Q was materially false and misleading because the 2018 10-K and Class Period 10-Qs “omitted to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading,” did not “fully comply with the requirements of Section 13(a) or 15(d) of the Exchange Act” and did not “fairly present[], in all material respects, the financial condition and result of operations of the Company” because the 2018 10-K and Class Period 10-failed to disclose all material facts necessary to make the statements in those filings not misleading. Specifically, Defendants failed to disclose to investors that: (i) Defendants were promoting ESKATA to patients using advertising materials that minimized the risks and overstated the efficacy of ESKATA in the hopes of luring patients to ask their dermatologist or other physician for the product; (ii) as a result, the Company was likely to face regulatory scrutiny; and (iii) as a result of the foregoing, Defendants’ positive statements about the Company’s business, operations, and prospects were materially misleading.

VII. THE TRUTH BEGINS TO EMERGE

157. Investors learned that Defendants’ DTC campaign misrepresented the risks and efficacy of ESKATA in violation of the FFDCA on June 20, 2019 (the “June 2019 Letter”), when the FDA publicly disclosed that it had sent an “untitled letter” to Defendants informing Defendants that the segment on The View “makes false or misleading claims” regarding ESKATA’s safety and efficacy in violation of the FFDCA.

158. Untitled letters identify violations of federal law caused by a company’s omission of risk information, minimization of risk information, broadening or inadequate communication

of indication, overstatement of efficacy or unsubstantiated claims. According to the FDA, untitled letters, among other things, request immediate correction of any regulatory violations that may not meet the threshold of regulatory significance for a “warning letter.” Although an untitled letter does not state that failure to promptly correct a violation may result in an enforcement action against the violator, the FDA is not obligated to warn individuals or firms about violations before taking enforcement action. Accordingly, an enforcement action can follow an untitled letter if the violations described in the untitled letter are not resolved.

159. The June 2019 Letter was seven pages long and very detailed. Indeed, a legal news website, Law360.com, observed that the June 2019 Letter appeared to be one of the longest untitled letters sent by the FDA in almost five years.⁷

160. The June 2019 Letter began by stating that that the marketing materials that the OPDP previously had warned Defendants about in the March 2018 Letter shared “certain similarities” with the segment from The View such that OPDP was “concerned that Aclaris is promoting Eskata in a manner that fails to adequately present the serious risks of the drug or describe the efficacy of the drug in a truthful and non-misleading manner despite [the March 2018 Letter’s] direction from OPDP.” In other words, the June 2019 Letter disclosed to investors that Defendants had implemented the DTC campaign *knowing* that the campaign violated the FFDCA because Defendants had been previously warned about the misleading nature of claims contained in the DTC campaign.

161. The June 2019 letter then said that the segment on The View was “especially concerning from a public health perspective because it fails to include information regarding the serious risks associated with ESKATA, which bears warnings and precautions related to the risks

⁷ Jeff Overley, *FDA Decries Drugmaker’s Promos on Facebook, ‘The View’*, Law360.com (Jun. 21, 2019), <https://www.law360.com/articles/1171679>.

of serious eye disorders . . . in the case of exposure to the eye and severe skin reactions including scarring.” The June 2019 Letter also stated that the segment’s use of before-and-after photographs “misleadingly represent[ed] that the typical patient treated with ESKATA will experience similar results, *i.e.*, complete clearance of all treated SK lesions.” The letter concluded by directing Defendants to stop using the segment to promote ESKATA, to submit a written response stating “whether you intend to comply with this request” and to submit a list of “all promotional materials . . . for ESKATA that contain violations such as those described above, and explaining your plan for discontinuing use of such materials.”

162. Defendants did not issue a press release or file a current report on Form 8-K with the SEC disclosing the June 2019 Letter. The public only learned of the letter when the *OPDP* disclosed it. Once the OPDP had disclosed the letter, Defendants informed news outlets (without issuing a press release or filing a Form 8-K) that Aclaris was “complying with all FDA requests and will formally respond to the agency by the June 28 deadline.” Defendants never publicly disclosed their response to the FDA.

163. On this news, the Company’s share price fell \$0.57 per share, or over 11%, over two consecutive trading sessions to close at \$4.54 per share on June 21, 2019, on unusually heavy trading volume.

164. With their scheme to market ESKATA using misleading advertising exposed, Defendants knew that they would need to destroy all of their marketing materials and launch a new campaign to promote ESKATA that told patients the truth: ESKATA did not effectively remove most raised SK, was painful and resulted in skin discolorations.

165. Defendants also knew that disclosing these facts meant that they could not successfully market ESKATA because these disclosures would confirm that ESKATA was no

better than any other treatment for raised SK and had all the downsides that Defendants' own research showed resulted in patients deciding not to treat their raised SK. Defendants thus decided that the only solution was to cease marketing ESKATA altogether.

166. Following the June 2019 Letter, the videos of the segment on The View were pulled from the sales representative's iPads. In addition, shortly after the June 2019 Letter became public, CW3 was present on a management call where he (and all Aclaris sales representatives) were instructed to destroy *all* ESKATA marketing materials. In addition, he was specifically told that all sales representatives were to go to the offices of physicians who had large stand-up banners promoting ESKATA and ask those officers to remove the banners. CW9 also recalled being told to destroy all ESKATA marketing materials, including banners and printed materials.

167. According to CW7, Defendants knew that the violations of the FFDCA identified in video of the segment on "The View" were present in *all* of the ESKATA's marketing materials. Rather than revise the marketing materials so that they complied with the FDA's specifications, CW7 said, Defendants Walker, Ruffo and Ali-Jackson decided to simply stop marketing ESKATA.

168. On August 8, 2019, Defendants issued a press release announcing Aclaris's financial results for the second quarter of 2019. The press release also disclosed that the Company was "[v]oluntarily discontinuing the commercialization of ESKATA® (hydrogen peroxide) Topical Solution, 40% (w/w) (ESKATA) in the United States due to the fact that revenues from product sales were insufficient for Aclaris to sustain continued commercialization as a result of the product not achieving sufficient market acceptance by physicians and patients." This was a materialization of the risk that Defendants would need to abandon ESKATA if it was

required to disclose to patients and investors that the treatment was limited in effectiveness, painful and resulted in skin discoloration.

169. On this news, the Company's share price fell \$0.15 per share, or over 14%, over two consecutive trading sessions to close at \$0.84 per share on August 12, 2019, on unusually heavy trading volume.

170. The fact that the future of the Company in its current state depended on successfully commercializing ESKATA was confirmed on September 5, 2019, when Defendants announced that they were terminating 86 employees, or over half the Company's staff, after Defendants announced a month earlier that Aclaris would no longer market ESKATA.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

171. Additional factors support a strong inference of the Individual Defendants' scienter during the Class Period in addition to those described in ¶¶1–30 and ¶¶52–150 above, including: (i) Individual Defendants' high-level positions within Aclaris, (ii) the misstatements and omissions of material facts concern the Company's core operations, about which the Individual Defendants were repeatedly questioned and spoke; and (iii) corporate scienter.

A. Individual Defendants' High-Level Positions Within Aclaris

172. Defendants Walker, Ruffo, Fair and Ali-Jackson each knew of the false and misleading nature of the statements discussed above, or at a minimum was reckless for not knowing these matters.

173. Defendant Walker was the CEO and Director of the Company at all relevant times. Aclaris identified Walker as an "Executive Officer" of the Company during the Class Period.

174. Defendant Ruffo was the CFO of the Company at all relevant times. Aclaris identified Ruffo as an "Executive Officer" of the Company during the Class Period.

175. Defendant Ali-Jackson was the CLO of the Company at all relevant times. Aclaris identified Ali-Jackson as an “Executive Officer” of the Company during the Class Period.

176. Defendant Fair was the CCO of the Company throughout the Class Period until February 7, 2019, after which Aclaris disclosed that he was “no longer employed by the Company.” Aclaris identified Fair as an “Executive Officer” of the Company during the Class Period until February 7, 2019.

177. As CEO, Walker was the head of Aclaris’s management and operations teams. Aclaris, by virtue of his responsibilities and activities as CEO and Director of the Company, was privy to all material information concerning the ESKATA Early Experience Initiative and Defendants’ direct-to-consumer marketing plan for ESKATA, including the advisory letters from the SEC and OPDP warning Defendants about misrepresenting ESKATA’s risks and efficacy. Moreover Defendant Walker was copied on Defendant Ali-Jackson response to the SEC’s letter in 2015 so Defendant Walker was aware of the contents of the SEC’s letter. Finally, Walker attended multiple sessions with CW7 and the other Individual Defendants, where CW7 raised concerns that the Company was misrepresenting Aclaris’s safety and effectiveness. These sessions were the result of concerns that had been raised during PRC meetings.

178. Defendant Ruffo, as CFO, was privy to, and participated in, all matters directly impacting the financial health of Aclaris, including patients’ reactions to ESKATA treatments in the ESKATA Early Experience Initiative, the March 2018 OPDP letter and the contents of Defendants’ direct-to-consumer marketing campaign for ESKATA. Finally, Ruffo attended multiple sessions with CW7 and the other Individual Defendants, where CW7 raised concerns

that the Company was misrepresenting Aclaris's safety and effectiveness. These sessions were the result of concerns that had been raised during PRC meetings.

179. Defendant Ali-Jackson, as CLO, likewise could not have failed to know about including patients' reactions to ESKATA treatments in the ESKATA Early Experience Initiative, the March 2018 OPDP letter and the contents of Defendants' direct-to-consumer marketing campaign for ESKATA. The essence of Ali-Jackson's job was to ensure that the Company's key drug candidate, ESKATA, was commercialized in compliance with all applicable regulations. Moreover, Ali-Jackson edited the script for the segment promoting ESKATA on The View "up until the last minute" and was present on set during the taping of the segment. Ali-Jackson also attended all of the Company's PRC meetings, where concerns about misleading marketing materials raised by CW7 and CW7's staff were discussed. Finally, Ali-Jackson attended multiple sessions with CW7 and the other Individual Defendants, where CW7 raised concerns that the Company was misrepresenting Aclaris's safety and effectiveness. These sessions were the result of concerns that had been raised during PRC meetings.

180. Finally, Defendant Fair, as CCO, organized and implemented the ESKATA Early Experience Initiative and oversaw all of the Company's marketing of ESKATA and thus could not have been unaware of patients' reactions to ESKATA treatments in the ESKATA Early Experience Initiative, the SEC and OPDP's advisory letters warning of misrepresenting the risks and effectiveness of ESKATA, and the contents of Defendants' direct-to-consumer marketing campaign for ESKATA. The essence of Fair's job was to ensure that the Company's key drug candidate, ESKATA, was commercialized successfully. Accordingly, to do his job, Fair must have been familiar with patients' reactions to ESKATA treatments in the ESKATA Early Experience Initiative, the SEC and OPDP's advisory letters warning of misrepresenting the risks

and effectiveness of ESKATA, and the regulations governing Defendants' direct-to-consumer marketing campaign for ESKATA. Accordingly, Fair knew that ESKATA was painful, limited in effectiveness and resulted in skin discoloration, and that Defendants direct-to-consumer marketing program for ESKATA misrepresented the product's safety and efficacy in violation of FFDCA. Finally, Fair attended multiple sessions with CW7 and the other Individual Defendants, where CW7 raised concerns that the Company was misrepresenting Aclaris's safety and effectiveness. These sessions were the result of concerns that had been raised during PRC meetings.

181. The statements of the CWs likewise make clear that Aclaris and the Individual Defendants were aware of the severity of the negative reactions patients had to ESKATA treatments during the ESKATA Early Experience Initiative and that the direct-to-consumer campaign for ESKATA misrepresented the risks and efficacy of the product. The CWs raised these issues to Aclaris's management throughout the Class Period, and those issues were presented to the Individual Defendants.

182. For example, the executive sales team met at Aclaris's headquarters approximately six months after ESKATA entered the marketplace, between August and October 2018. At that meeting, the members of the executive sales team discussed, among other things, the complaints sales representatives had received from physicians and patients about ESKATA's adverse side effects and ineffectiveness, including that ESKATA took many *more* applications to achieve any results than the physicians had been told when they were sold the product. Defendants Walker and Fair attended this meeting, along with other members of the Company's senior leadership.

183. Finally, the CWs stated that the problems with ESKATA's efficacy, pain and skin discoloration were known throughout Aclaris, a very small Company that had only received FDA approval of one product that the Company had developed.

184. Defendants Walker and Ruffo each signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") for each SEC filing referenced in Section VI.G above. In these certifications, Walker and Ruffo each certified that he had reviewed the SEC filings and determined that they contained no false or misleading statements or omissions.

B. Core Operations

185. The fraud alleged herein relates to the core business and operations of Aclaris so knowledge of the fraud may be imputed to Defendants. As explained in ¶¶4, 56–57, 62, nothing was more important to Aclaris during the Class Period than ESKATA sales. Accordingly, it is appropriate to presume that Defendants were apprised of, had access to, or had actual knowledge of all material information related to ESKATA during the Class Period, including the material information that was improperly withheld and/or misrepresented to investors.

186. Further, by virtue of their receipt of information reflecting the true facts regarding Aclaris's operations and its marketplace, as well as their control over and/or receipt of the Company's materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning Aclaris, the Individual Defendants were active and culpable participants in the fraudulent scheme alleged herein. The Individual Defendants knew of and/or recklessly disregarded the falsity and misleading nature of the information, which they caused to be disseminated to the investing public. The fraud as described herein could not have been perpetrated without the knowledge and/or recklessness and complicity of personnel at the highest level of the Company, including the Individual Defendants.

C. Corporate Scierter

187. The allegations above also establish a strong inference that Aclaris as an entity acted with corporate scierter throughout the Class Period, as its officers, management, and agents, including, but not limited to, the Individual Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing Aclaris's true operating condition and present and expected financial performance from the investing public. By concealing these material facts from investors, Aclaris maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

IX. CLASS ACTION ALLEGATIONS

188. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Aclaris securities between May 8, 2018 and June 20, 2019, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

189. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aclaris' common shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least

hundreds or thousands of members in the proposed Class. Millions of Aclaris common stock were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Aclaris or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

190. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

191. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

192. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Aclaris; and
- c) to what extent the members of the Class have sustained damages and the proper measure of damages.

193. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and

burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. LOSS CAUSATION

194. On June 19, 2019, Aclaris's stock price closed trading at \$5.11 per share. On June 20, 2019, the FDA released the OPDP letter, which disclosed for the first time that Defendants had been warned in March 2018 that their marketing materials inappropriately exaggerated ESKATA's benefits while concealed its risks, and that a taped interview segment from The View promoting ESKATA violated the FFDCA. On this news, Aclaris's share price fell \$0.57 per share, or over 11%, over two consecutive trading sessions to close at \$4.54 per share on June 21, 2019.

195. Defendants knew when they created their advertising for ESKATA that the images and text they were using violated federal law since they had been warned by the SEC as far back as 2015 not to use "before and after pictures" to demonstrate ESKATA's benefits and been warned by the OPDP in March 2018 that their marketing materials for ESKATA inappropriately overstated the treatment's benefits and omitted or misrepresented important risk information.

196. Defendants also knew that if the FDA ever took action against them for these violations of the FFDCA, Defendants may not be able to effectively market ESKATA because if consumers knew that the treatment was limited in effectiveness, painful and left scars or other discolorations on skin, patients would not undergo the treatment.

197. Accordingly, by failing to publicly disclose that they were using advertising to promote ESKATA as part of a scheme to violate the FFDCA, Defendants concealed the risk that they would need to abruptly discontinue ESKATA.

198. The risk that Defendants would have to discontinue ESKATA materialized on August 8, 2019, when Defendants issued a press release announcing Aclaris's financial results for the second quarter of 2019. The press release disclosed that Defendants were voluntarily discontinuing the commercialization of ESKATA in the United States. Defendants misleadingly attributed their decision to stop selling ESKATA to "the fact that revenues from product sales were insufficient for Aclaris to sustain continued commercialization," when in reality the product was removed from the market because Defendants could no longer market the drug without highlighting for customers that it was limited in effectiveness, painful and caused skin discolorations.

199. On this news, the Company's share price fell \$0.15 per share, or over 14%, over four consecutive trading sessions to close at \$0.8280 per share on August 13, 2019, on unusually heavy trading volume.

200. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

201. During the Class Period, Plaintiff and the Class purchased Aclaris' securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

XI. APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

202. The market for Aclaris' securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Aclaris' securities traded at artificially inflated prices during the Class Period. On July

11, 2018, the Company's share price closed at a Class Period high of \$20.89 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Aclaris' securities and market information relating to Aclaris, and have been damaged thereby.

203. During the Class Period, the artificial inflation of Aclaris' shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Aclaris' business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Aclaris and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company's shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

204. At all relevant times, the market for Aclaris' securities was an efficient market for the following reasons, among others:

- a) Aclaris shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;
- b) As a regulated issuer, Aclaris filed periodic public reports with the SEC and/or the NASDAQ;
- c) Aclaris regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the

national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

d) Aclaris was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

205. As a result of the foregoing, the market for Aclaris' securities promptly digested current information regarding Aclaris from all publicly available sources and reflected such information in Aclaris' share price. Under these circumstances, all purchasers of Aclaris' securities during the Class Period suffered similar injury through their purchase of Aclaris' securities at artificially inflated prices and a presumption of reliance applies.

206. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

XII. NO SAFE HARBOR

207. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint.

The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward-looking, they were not identified as “forward-looking statements” when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Aclaris who knew that the statement was false when made.

COUNT I

(Violations of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

208. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

209. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

210. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to

defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Aclaris securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Aclaris securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

211. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Aclaris securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about sotagliflozin.

212. By virtue of their positions at Aclaris, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

213. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Aclaris, the Individual Defendants had knowledge of the details of Aclaris's internal affairs.

214. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Aclaris. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Aclaris's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Aclaris securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Aclaris's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Aclaris securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

215. During the Class Period, Aclaris securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Aclaris securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or

otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Aclaris securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Aclaris securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

216. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

217. Plaintiffs and members of the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Aclaris's securities. Plaintiffs and the Class would not have purchased the Company's securities at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon disclosure of Defendants' wrongful conduct.

COUNT II

(Violations of Section 20(a) of The Exchange Act Against the Individual Defendants)

218. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

219. Individual Defendants acted as controlling persons of Aclaris within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/ or awareness of the Company's

operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

220. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the transactions giving rise to the securities violations as alleged herein, and exercised the same.

221. As set forth above, Aclaris and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XIII. PRAYER FOR RELIEF

222. WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiffs as class representatives pursuant to Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory and punitive damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon;

C. Awarding Plaintiffs and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

D. Awarding Plaintiffs and the other Class members such other relief as this Court may deem just and proper.

XIV. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: January 24, 2020

Respectfully submitted,

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